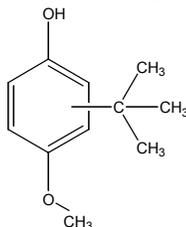


BUTYLATED HYDROXYANISOLE (BHA)

CAS No. 25013-16-5

First Listed in the *Sixth Annual Report on Carcinogens*



CARCINOGENICITY

Butylated hydroxyanisole (BHA) is *reasonably anticipated to be a human carcinogen* based on sufficient evidence of carcinogenicity in experimental animals (IARC 1986, 1987). When administered in the diet, butylated hydroxyanisole induced papillomas and squamous cell carcinomas of the forestomach in rats of both sexes and male Syrian Golden hamsters. There is no evidence that butylated hydroxyanisole is carcinogenic to mice when administered topically or by subcutaneous or intraperitoneal injection. In a study that was reported to the IARC Working Group as an abstract and became available subsequent to the meeting of the Working Group, administration of butylated hydroxyanisole in the diet induced papillomas and carcinomas of the forestomach in mice (IARC 1986, Masui *et al.* 1986).

No data were available to evaluate the carcinogenicity of butylated hydroxyanisole in humans (IARC 1986, 1987).

PROPERTIES

BHA, a white or slightly yellow waxy solid, is a mixture of 3-*tert*-butyl-4-hydroxyanisole and 2-*tert*-butyl-4-hydroxyanisole. It melts at 45 to 63°C and has a boiling point of 264 to 270°C. BHA is flammable, with a flash point of 156°C. BHA has a faint characteristic odor. It is insoluble in water; it is freely soluble in 50% ethanol, other alcohols, propylene glycol, petroleum ether, and fats and oils. Commercial food-grade BHA is generally a mixture with >85% 3-*tert*-butyl-4-hydroxyanisole (3-BHA) and <15% 2-*tert*-butyl isomer (2-BHA) (Lam *et al.* 1979, IARC 1986). Food-grade BHA is >98% pure (NRC 1972). BHA exhibits antioxidant properties as a scavenger of free radicals. It degrades after prolonged exposure to sunlight. When heated to decomposition, BHA emits acrid and irritating fumes.

USE

The primary use for BHA is as an antioxidant and preservative in food, food packaging, animal feed, and cosmetics, and in rubber and petroleum products (HSDB 2000). Antioxidants are used to delay the deterioration of food flavors and odors and substantially increase the shelf life of many foods (Kirk-Othmer 1978). Since 1947, it has been added to edible fats and fat-containing foods for its antioxidant properties; it prevents food from becoming rancid and developing objectionable odors (Lam *et al.* 1979, IARC 1986). Antioxidants in cooking oils are used primarily for their carry-through and stabilizing effects on fried products; these effects are essential to the success of several commercial fried foods (Kirk-Othmer 1978). BHA is added to butter, lard, meats, cereals, baked goods, sweets, beer, vegetable oils, potato chips, snack foods,

nuts and nut products, dehydrated potatoes, and flavoring agents. It is used in sausage, poultry and meat products, dry mixes for beverages and desserts, glazed fruits, chewing gum, active dry yeast, defoaming agents for beet sugar and yeast, and emulsion stabilizers for shortenings (Kirk-Othmer 1979b, 1981b, IARC 1986). BHA is widely used in the food industry. It is used in foods cooked or fried in animal oils because of its high thermal stability and its ability to remain active in baked and fried foods (LeFaux 1968; Kirk-Othmer 1981a). Its antioxidant properties are not lost during cooking; BHA-stabilized ingredients may be used to produce stabilized products (Kirk-Othmer 1979b). BHA stabilizes the petroleum wax coatings of food packaging (Sax and Lewis 1987). BHA is considered a GRAS (generally recognized as safe) compound by the FDA when the content of the antioxidant is not greater than 0.02% w/w of the total fat or oil content of the food.

Antioxidants retard the oxidation of vitamins A and E, carotene, xanthophyll pigments, rendered fats, and vegetable oils in animal feeds; BHA is one of the primary antioxidants used in these feeds (Kirk-Othmer 1978). It is an effective stabilizer for essential oils, paraffin, and polyethylenes (LeFaux 1968).

BHA is used as a preservative and antioxidant in pharmaceutical preparations and cosmetic formulations containing fats and oils (Osol 1980). Cosmetic-grade BHA reportedly contains a minimum of 90% 3-BHA and approximately 8% 2-BHA (IARC 1986). In a 1981 FDA survey, BHA was reported to be used in 3,217 to 21,279 cosmetic formulations; the majority (88%) of the reported concentrations was $\leq 0.1\%$ (IARC 1986). One product, a lipstick, was reported to contain $>10\%$ BHA. In this survey, lipstick formulations (1,256 products) represented the highest use of BHA, with eye shadows being the next highest (410 products). A widely used antioxidant mixture for cosmetics contained 20% BHA, 6% propyl gallate, 4% citric acid, and 70% propylene glycol (Kirk-Othmer 1979a, IARC 1986).

PRODUCTION

The 1997 *Directory of Chemical Producers* lists two producers of BHA; no volumes, however, were disclosed (SRI 1997). In its latest and final editions, USITC (1993-1995) did not list BHA, but for 1990 and 1991, two manufacturers of the chemical were identified (USITC 1991, 1993). In 1982, the same number of major BHA producers were found in the United States (Giragosian 1982, IARC 1986). Suppliers of the chemical, however, were abundant. The 1998 *Chemical Buyers Directory* listed 11 such companies, while *Chemyclopedia 98* listed three (Tilton 1997, Rodnan 1997). Chem Sources (2001) listed 21 current suppliers in the United States.

EXPOSURE

Potential for consumer exposure to BHA by ingestion and dermal contact is widespread. In 1975, the estimated average daily intake of BHA in the diet was 4.3 mg (IARC 1986). It is a widely used food additive in products containing vegetable oils or animal fats. It retains its antioxidant properties even at high temperatures. The general population may be exposed to BHA in butter, lard, meats, cereals, baked goods, sweets, beer, vegetable oils, potato chips, snack foods, nuts, dehydrated potatoes, flavoring agents, sausage, poultry and meat products, dry mixes for beverages and desserts, glazed fruits, chewing gum, active dry yeast, defoaming agents for beet sugar and yeast, and emulsion stabilizers for shortenings. The estimated U.S. consumption of BHA in food increased to 660,000 lb/yr during 1970 to 1982, up from 374 lb/yr in 1960 (Anonymous 1984, IARC 1986). Reported annual consumption for BHA in the mid 1970s was

990,000 lb compared with 3.1 million lb for butylated hydroxytoluene (BHT) (Kirk-Othmer 1978). Industrial use of BHA has largely been replaced by *tert*-butylhydroquinone (TBHQ) (Kirk-Othmer 1980).

Potential dermal exposure exists for the population that uses cosmetics, especially lipstick and eye shadow. BHA is also used as an antioxidant for some rubber and petroleum products, and it is a stabilizer for vitamin A.

Potential occupational exposure exists for workers in certain industries, including food producers, animal feed producers, livestock producers, cosmetic manufacturers, some petroleum workers, and rubber producers and those who handle the end products such as tires. Fast food service personnel who normally cook and serve fried and oily foods have the potential for high exposure to BHA. BHA is volatile at 150 to 170°C and is readily lost from thermal processes generating steam (Kirk-Othmer 1980). The National Occupational Exposure Survey (1981-1983) estimates that 32,553 total workers, including 7,933 women, are potentially exposed to BHA (NIOSH 1984).

REGULATIONS

EPA regulates butylated hydroxyanisole under the Food, Drug, and Cosmetic Act (FD&CA).

FDA also regulates use of BHA under FD&CA as a direct or indirect food ingredient.

OSHA regulates BHA under the Hazard Communication Standard and as a chemical hazard in laboratories. Regulations are summarized in Volume II, Table 27.

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